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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,421	KRISHNAN ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,24 and 720* is/are pending in the application.

4a) Of the above claim(s) *2-4,8,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,9-18 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 02 April 2007, with respect to the rejection(s) of claim(s) 1, 5, 7, 9–18 and 24 under 35 U.S.C. 103(a) as being unpatentable over Vachon, U.S. Patent 5,861,023 and in view of McAuslan, U.S. Patent 4,836,884 and Helland et al., U.S. Patent 5,318,572 (claims 1, 5, 7, 9, 10, 17, 18 and 24) and Mar et al., U.S. Patent 5,411,544 and in view of McAuslan, U.S. Patent 4,836,884 and Helland et al., U.S. Patent 5,318,572 (claims 11–16) and Vachon, U.S. Patent 5,861,023 and McAuslan, U.S. Patent 4,836,884 and Helland et al., U.S. Patent 5,318,572 and further in view of MacGregor, U.S. Patent 4,936,317 (claims 17 and 18) and have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejection is made in view of a different interpretation of the previously applied references and a newly found prior art reference.

Requirement For Information

2. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the Examiner has determined is reasonably necessary to the examination of this application: The definition of a pseudo-intimal layer, how it is formed and what constitutes a pseudo-intimal layer on the surface of the lead when the lead is exposed to a bloodstream.

3. The information is required to extend the domain of search for prior art. Limited amounts of art related to the claimed subject matter are available within the Office, and are generally found in class 607 and subclasses 122, which describe catheter or endocardial (inside

heart) type. A broader range of art to search is necessary to establish the level of knowledge of those of ordinary skill in the claimed subject matter art of a pseudo-intimal layer.

4. The information is required to document the level of skill and knowledge in the art of a pseudo-intimal layer.

5. The information is required to complete the background description in the disclosure by documenting a pseudo-intimal layer.

6. In response to this requirement, please provide a list of keywords that are particularly helpful in locating publications related to the disclosed art of a pseudo-intimal layer.

7. In response to this requirement, please provide copies of each publication which any of the applicants authored or co-authored and which describe the disclosed subject matter of a pseudo-intimal layer.

8. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

9. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

10. This requirement is an attachment of the enclosed Office Action. A complete reply to the enclosed Office Action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office Action.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

12. Claims 1, 5, 7, 9–18 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claim 1, 11 and 17 the term "pseudo-initimal layer" is vague, confusing and indefinite. It is unclear what a pseudo-initimal layer is and how it is formed; the Applicant's specification does not clearly explain either. Additionally, Applicant's teaching that "RGD which promotes the adhesion of endothelial cells" (page 5, lines 25–26) conflicts with *Dorlands Medical Dictionary* definition of pseudointima which states "in a blood vessel graft or vascular prosthesis, a new layer on the intimal surface that consists of cells ***other than*** endothelial cells, such as plasma proteins or collagen." [emphasis Examiner's] Consequently, the limitation is confusing regarding what a pseudo-initimal layer really is.

Also, in claim 1, the limitation "...the electrode ... have an outer surface adapted to passively prevent formation of clots" seems to contradict the limitation of "a textured coating" in that a textured coating commonly implies that something will adhere or be attracted to the textured area. This is born out in the limitation of claim 7, which states, "the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and

tightly adherent biologic surface." Given that Applicant has not specifically defined "a uniform and tightly adherent biologic surface," and in the broadest reasonable interpretation, it is the Examiner's position that "a uniform and tightly adherent biologic surface" is a type of blood clot based on the definition in *MedTerms Medical Dictionary* which defines a blood clot as "blood that has been converted from a liquid to a solid state." Accordingly, it appears that the limitation in claim 1 of "passively prevent formation of clots" and the limitation in claim 7 of "the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface" are conflicting.

Similarly in claim 11, the phrase "a textured outer surface" and "to passively prevent formation of clots" seems to contradict each other in that a textured coating commonly implies that something will adhere or be attracted to the textured area. It is unclear how both limitations can be simultaneously realized.

Claim Rejections - 35 USC § 102/103

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 5, 7, 9–18 and 24 rejected under 35 U.S.C. 102(b) as anticipated by Helland et al., U.S. Patent 5,318,572 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Helland et al., U.S. Patent 5,318,572 in view of McAuslan, U.S. Patent 4,836,884 or Kitrilakis, U.S. Patent 3,700,380.

17. Regarding claims 1, 9, 10, 11, 14, 16, 17 and 24, Helland et al. disclose a lead body and an electrode (e.g., FIG. 1);

an outer surface adapted to passively prevent formation of clots (e.g., for a lead column 4, lines 8–10; for an electrode column 3, lines 31–33) (It is noted that, in view of claim 7, and as discussed in the 35 U.S.C. 112 2nd Paragraph rejection above, it is the Examiner's position that the Applicant's specification and the prior art of Helland et al. initially form "a uniform and tightly adherent biologic surface on the electrode.)

a pseudo-intimal layer is inherently formed on the outer surface because silicone rubber and polyurethane are materials of low thrombogenicity that encourage a buildup of connective tissue to shield the lead and later leave it as a neutral foreign body. (It is noted that this is

consistent with the Applicant's specification which states "Again, this layer on the lead acts so that the bloodstream does not act unfavorably to the presence of a foreign body by triggering clot formation."),

a textured coating including titanium microspheres (e.g., column 6, lines 29–30 and 37–38; column 5, lines 61–62; column 10, lines 3 and 8–12).

18. With respect to claims 5, 7, 12, 13, 15 and 18, Helland et al. disclose titanium microspheres have a diameter of between 75–100 μm (claims 5 and 13) (e.g., column 5, lines 62–66; column 10, lines 19–20) and are dimensioned to attract circulating blood cells (claims 7, 15 and 18) and trap blood cells (claim 12) (column 5, lines 8–22; column 6, lines 14–17).

19. In the alternative, claims 1, 11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al., U.S. Patent 5,318,572 in view of McAuslan, U.S. Patent 4,836,884 or Kitrilakis, U.S. Patent 3,700,380.

Helland et al. do not explicitly disclose a pseudo-intimal layer is formed. However, McAuslan discloses implantable devices having an outer surface so that a pseudo-intimal layer is formed (e.g., column 2, lines 24–27, 35–38, 49–50 and 65-67; column 3, lines 1–18) to improve thromboresistance. (It is noted that the teaching of McAuslan clearly discloses the same field of endeavor as Helland et al. in that it applies to implantable materials.) Or, Kitrilakis discloses a surface forms a tenacious base for a pseudo-intimal layer to be formed (e.g., ABSTRACT; column 3, lines 16 –20) to effectively, efficiently, and considerably reduce the interim risks of blood trauma, thrombus formation and thromboemboli. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Helland et al. to include the formation of a pseudo-intimal layer, as taught by

McAuslan or Kitrilakis to improve thromboresistance and to effectively, efficiently, and considerably reduce the interim risks of blood trauma, thrombus formation and thromboemboli.

20. Claims 1, 5, 7, 9–18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al., U.S. Patent 6,370,427 in view of Helland et al., U.S. Patent 5,318,572.

21. Regarding 1, 9, 10, 11, 14, 16 and 24, Alt et al. disclose a lead body and an electrode (e.g., FIGS. 1 and 3–4); an outer surface adapted to passively prevent formation of clots (e.g., for a lead column 11, lines 9–11 and column 14, lines 21–22; for an electrode column 12 lines 41–46);

a pseudo-intimal layer is formed (e.g., column 11, lines 34–37 where this cited reference is consistent with Applicant's specification which states "Again, this layer on the lead acts so that the bloodstream does not act unfavorably to the presence of a foreign body by triggering clot formation.").

Alt et al. do not disclose the electrode has a textured coating including titanium microspheres. However, Helland et al. disclose an electrode having a textured coating including titanium microspheres (e.g., column 6, lines 29–30 and 37–38; column 5, lines 61–62; column 10, lines 3 and 8–12) to enhance electrode stabilization. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Alt et al. to include a textured coating including titanium microspheres, as taught by Helland et al. to enhance electrode stabilization.

22. With respect to claims 5, 7, 12, 13, 15 and 18, Alt et al. do not disclose titanium microspheres have a diameter of between 75–100 μm (claims 5 and 13) and are dimensioned to

attract circulating blood cells (claims 7, 15 and 18) and trap blood cells (claim 12). However, Helland et al. disclose titanium microspheres have a diameter of between 75–100 μm (e.g., column 5, lines 62–66; column 10, lines 19–20) and are dimensioned to attract circulating blood cells and trap blood cells (column 5, lines 8–22; column 6, lines 14–17) to optimize the active surface area and enhance electrical efficiency, minimize the amount of irritation of the endocardial tissue and provide a desirable environment for optimum therapy delivery. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Alt et al. to include titanium microspheres have a diameter of between 75–100 μm and are dimensioned to attract circulating blood cells and trap blood cells to optimize the active surface area and enhance electrical efficiency, minimize the amount of irritation of the endocardial tissue and provide a desirable environment for optimum therapy delivery.

Conclusion

23. This Office Action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office Action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office Action.

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on 7:30 a.m. - 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
June 18, 2007
18 June 2007

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6/18/7

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